



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/657,940

09/09/2003

Jason D. Meridew

5490-000341

1613

27572 7590 06/14/2007
HARNES, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

EXAMINER

SHAFFER, RICHARD R

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

06/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/657,940	Applicant(s) MERIDEW ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-21 and 23-44 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12,16-21,23-38 and 40-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 12, 16-21, 23-31, 37, 38 and 40-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 recites the limitation "an aperture" and "a slot" while claim 9 already recites a "longitudinal channel" which corresponds to the "aperture." The limitations of claims 11 and 12 will be given no patentable weight during this state of prosecution.

Claims 16, 20 and 36 recite the limitation, "so as to." There is no direct support that it is this arrangement that prevents rotation rather than the staple merely prevents rotation. Claims 17-19, 21, 23-31, 37, 38 and 40-44 are rejected for being dependent upon a claim rejected under 35 U.S.C. 112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim s 21, 25 and 26 recite the limitation "the slot." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. As explained in the 35 U.S.C. 112, first paragraph rejection, applicant appears to be positively reciting the human body.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-8, 16-19, 32-38 and 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohrs et al (US Patent 6,224,631).

Kohrs et al disclose a cylindrical, resorbable (**Column 3, Lines 40-47**) implant/bone screw (**10, Figure 1**) having a threaded (**7**) exterior; a pair of opposed channels (**24a/b**);

Art Unit: 3733

[First Interpretation] a driver (506, Figures 16 and 17) also having a threaded/cutting portion (526, 527) and a driving portion (508 or the abutment surface between the threaded prongs); a fastener (40, Figure 1) also having threads (43) and configured to be disposed within the channels. **[Second Interpretation]** a staple (506, Figures 16 and 17) an aperture is inherent between the abutment/graft holding surface (between prongs) of the staple and the surface of the bone screw (10) should soft tissue pass through (soft tissue is not positively recited). Kohrs et al further disclose that disposing additional graft material inside the implant is known.

Kohrs et al further disclose a method

[First Interpretation] of forming an aperture within a bone; channels (24a/b) in an exterior surface of the implant (10); coupling the implant to a driver (506); driving the implant into the aperture; forming an implant engaging surface within the aperture; and coupling soft tissue to the implant (inherent) because the body is full of soft tissue, the device is clearly indirectly coupled to soft tissue located elsewhere in the body.

[Second Interpretation] of forming an aperture within a bone; driving a threaded implant (10) into a bone aperture; the threads of the implant (10) define arcuate grooves between them; inserting a staple (506) into a slot defined in the threaded surface, whereby the staple bindingly intersects the groove and engages both the implant and bone aperture; and interposing a graft between the implant and a surface defining the staple (additional graft material may be inserted inside the additional passages of implant (10)).

Claims 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenfield (US Patent 5,584,835).

Greenfield discloses a system comprising: an implant (50) having outer threads; the exterior threaded portion defines a longitudinal channel within it; a driver (205) having a cutting portion (207) and a driving portion (unseen handle or body portion to allow for easier pressure application); a staple (51) having an upward locking surfaces (55) to engage with internal locking surfaces with in implant (50); and a graft (63) interposed between the staple (51) and implant (50).

Claims 20, 21 and 23-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackson (US Patent 6,835,206).

Jackson discloses a method (**Figure 5**) of forming an implant engaging surface within bone by rotating a driver (71); driving a threaded (31) implant (10); and inserting a staple (83) into two longitudinal channels thereby intersecting the grooves defined by the threading of implant (10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson.

Jackson discloses all of the claimed limitations except for the bone screw being made of resorbable materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a bioabsorbable material since it has been held that such is within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed March 26th, 2007 have been fully considered but they are not persuasive. In regard to the anticipation rejection by Kohrs et al, applicant largely argues intended use in regards to a graft engaging surface and the ability of the threads of the staple to intersect the arcuate groove (it's fully capable if offset and inherently offset during periods of insertion and removal). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In regard to the prior art reference to Greenfield, several claims have been withdrawn as being anticipated by Greenfield with the remaining claims subject to a slightly different interpretation.

The remaining claim arguments are moot in view of the new grounds of rejection based upon the prior art reference to Jackson.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
June 11th, 2007



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER